

## **EXTRA STRENGHT HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet**

### **TOPCO ASSOCIATES LLC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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## **EXTRA STRENGTH HEADACHE RELIEF**

### **Drug Facts**

<b>Active ingredient (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 250 mg	Pain reliever
Aspirin 250 mg (NSAID) *	Pain reliever
Caffeine 65 mg	Pain reliever aid

\* nonsteroidal anti-inflammatory drug

### **Uses**

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- sinusitis
- toothache
- premenstrual & menstrual cramps

### **Warnings**

#### **Reye's syndrome**

Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

#### **Allergy alert**

Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

### **Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

### **Stomach bleeding warning**

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

### **Caffeine warning**

The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

### **Do not use**

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

### **Ask doctor before use if**

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis or kidney disease
- you are taking a diuretic
- you have asthma

### **Ask a doctor or pharmacist before use if you are taking**

- any other drug containing an NSAID (prescription or nonprescription)

- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition
- a blood thinning (anticoagulant) or steroid drug

**Stop use and ask doctor if**

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding
  - feel faint
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms appear

These could be signs of a serious condition

**If pregnant or breast-feeding** ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children****Overdose Warning**

In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms. 1(800) 222-1222

**Directions**

- **do not use more than directed (see Overdose Warning)**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

**Other information**

- store at controlled room temperature 20° - 25° C (68° - 77° F)
- read all product information before using. Keep this box for important information

**Inactive ingredients**

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc

**Questions or comments**

**1-888-333-9792**

**PRINCIPAL DISPLAY PANEL**

COMPARE TO THE ACTIVE INGREDIENTS OF EXCEDRIN®

EXTRA STRENGTH

HEADACHE RELIEF

ACETAMINOPHEN, ASPIRIN (NSAID) AND CAFFEINE

PAIN RELIEVER / PAIN RELIEVER AID

**2**

100 ct  
BOTTLES  
INSIDE

**TWIN PACK**

**+TopCare**  
health®

NDC 36800-675-20

COMPARE TO EXCEDRIN®  
EXTRA STRENGTH CAPLETS  
ACTIVE INGREDIENTS†

**EXTRA STRENGTH**

# Headache Relief

**ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE**

PAIN RELIEVER • PAIN RELIEVER AID



actual size

**+TopCare**  
health®

COMPARE TO EXCEDRIN®  
EXTRA STRENGTH CAPLETS  
ACTIVE INGREDIENTS†

**EXTRA STRENGTH**

# Headache Relief

**ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE**

PAIN RELIEVER • PAIN RELIEVER AID



actual size

**200 TOTAL CAPLETS**

NDC 36800-675-01

COMPARE TO EXCEDRIN® EXTRA  
STRENGTH ACTIVE INGREDIENTS†

EXTRA STRENGTH

# Headache Relief

ACETAMINOPHEN, ASPIRIN (NSAID) & CAFFEINE  
PAIN RELIEVER • PAIN RELIEVER AID

100 CAPLETS

actual size

## EXTRA STRENGTH HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-675
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL (capsule shaped, biconvex)	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-675-20	2 in 1 CARTON	10/28/2020	
1	NDC:36800-675-10	100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-675-01	1 in 1 CARTON	01/21/2021	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	10/28/2020	

**Labeler** - TOPCO ASSOCIATES LLC (006935977)

Revised: 11/2021

TOPCO ASSOCIATES LLC